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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/993,501

Applicant(s)

ANDERSON ET AL.

Examiner

Frank W Lu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group 1, claims 1-6 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that: (1) "all of the claims are classified together in class 435, subclass 7.2."; (2) "all of the claims in Group II are dependent on claim 1, so Group II will be allowable if claim 1 is allowed."; and (3) "a search of claims of Group II is integral to a search of the claims of Group I, since the two groups differ only in the step of comparing the data to know microorganism data.".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I and II will be examined. First, the restriction was not based on the classification of Groups I and II. Second, although the searches for Groups I and II are similar, their searches are not coextensive. For example, the search required for Group II such as step (b) in claim 7 is not required for Group I. Third, the examiner agreed with applicant "Group II will be allowable if claim 1 is allowed.". The examiner will combine Groups I and II together if claim 1 is allowable.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

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***Priority***

2. Applicant is required to update the prior application(s) in the first sentence of the specification since US Patent applications 09/571,274 and 09/265,541 have been issued by the office.

***Information Disclosure Statement***

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objections***

4. Claim 5 is objected to because of the following informality: "nucleic acid" in last line of the claim should be "said nucleic acid".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is rejected as vague and indefinite because preamble of the method (the goal of the method) does not correspond to the method steps listing in the claim. Since claim 1 is directed to a method for determining a characteristic of a microorganism, there is no phrase "a characteristic of a microorganism" in the method steps of the claim. Please clarify.

8. Claim 2 is rejected as vague and indefinite because it is unclear what it intended. Does this claim mean that said microorganism is not cultured before adding to the centrifuge tube or this claim mean something else? Please clarify.

9. Claim 3 recites the limitation "single stranded DNA, single stranded RNA or double stranded RNA" in the claim. There is insufficient antecedent basis for this limitation in the claim since it has been known that restriction enzymes do not digest these nucleic acids. Please clarify.

10. Claim 5 is rejected as vague and indefinite because it is unclear whether claim 5 follows step (b) of claim 1 or step (c) of claim 1 since claim 5 also has a digestion step. If claim 5 follows step (b) of claim 1, is step (c) of claim 1 a duplication step of the digestion step of claim 5? If claim 5 follows step (c) of claim 1, claim 1 and claim 5 will not correspond each other. Please clarify.

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***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sambrook *et al.*, (Molecular Cloning, A Laboratory Manual, Second Edition, pages 1.25-1.30, 1989).

Sambrook *et al.*, teach small-scale preparation of plasmid DNA. 1.5 ml of bacteria culture was harvested in a microfuge tube by centrifugation and then plasmid DNA was isolated by either alkali lysis method or lysis by boiling method. The isolated double strand plasmid DNA as recited in claim 3 was digested with restriction enzyme(s) as recited in claim 6 and the digested DNA fragments were analyzed by gel electrophoresis (see pages 1.25-1.30. Specifically see pages 1.25 and 1.28). Note that: (1) the microfuge tube was considered as centrifuge tube comprising an upper region, a middle region and a low region wherein an inner diameter of said upper region was larger than an inner diameter of said middle region and wherein an inner diameter of said middle region was larger than an inner diameter of said low region as recited in claim 1 (for the size and shape of the microfuge tube, see Figures 1.2 and 1.3); and (2) after the gel electrophoresis, the number of digested fragments of plasmid could be determined as recited in claim 1.

Therefore, Sambrook *et al.*, teach all limitations recited in claims 1, 3, and 6.

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***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook *et al.*, (1989) as applied to claims 1, 3, and 6 above, and further in view of Maniatis *et al.*, (Molecular Cloning, A Laboratory Manual, pages 161, 1982).

The teaching of Sambrook *et al.*, have been summarized previously, *supra*.

Sambrook *et al.*, do not disclose to stain the digested DNA fragments.

Maniatis *et al.*, teach to detect nucleic acids in gel by incorporating ethidium bromide into both gel and the running buffer or to run the gel in the absence of ethidium bromide and stain the DNA on the gel after electrophoresis is complete (see page 161).

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Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used ethidium bromide to stain nucleic acid fragments in the gel in view of the references of Sambrook *et al.*, and Maniatis *et al.*. One having ordinary skill in the art would have been motivated to detect the digested nucleic acid fragments in the gel by incorporating ethidium bromide into both gel and the running buffer or staining the DNA in the gel with ethidium bromide after electrophoresis was complete because visualizing DNA in a gel by the use of a fluorescent dye ethidium bromide was the most convenient, simplest, and common method in the laboratory. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to stain the digested nucleic acid fragments in the gel.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook *et al.*, (1989) as applied to claims 1, 3, and 6 above, and further in view of Burgoyne (US Patent No.5,756,126, filed on June 7, 1995).

The teaching of Sambrook *et al.*, have been summarized previously, *supra*.

Sambrook *et al.*, do not disclose to amplify immobilized extracted nucleic acids or digest immobilized extracted nucleic acids with a restriction enzyme.

Burgoyne teach to amplify immobilized extracted nucleic acids or digest immobilized extracted nucleic acids with a restriction enzyme (see Examples 1-3 in columns 15-21).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have amplified



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immobilized extracted nucleic acids or have digested immobilized extracted nucleic acids with a restriction enzyme in view of the prior art of Sambrook *et al.*, and Burgoyne. One having ordinary skill in the art would have been motivated to amplify immobilized extracted nucleic acids or digest immobilized extracted nucleic acids in order to test whether nucleic acids in immobilized form, like nucleic acids in solution form, could be used for subsequent analysis such as amplification and digestion. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to amplify immobilized extracted nucleic acids or digest immobilized extracted nucleic acids.

### ***Conclusion***

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
November 5, 2002



ETHAN C. WHISENANT  
PRIMARY EXAMINER